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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

August 9, 2002

WARNING LETTER

NWE-26-02W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Robin A. Mott, Owner
Better Way Kids
16 Warren Court
Cranston, RI 02920

Dear Ms. Mott,

The U.S. Food and Drug Administration (FDA) conducted an inspection of your firm, Better Way Kids located at 16 Warren Street, Cranston, RI on May 28 and June 6, 2002. Labeling for your firm's product Calm Focus was collected during the inspection and a review of that labeling indicates serious violations of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act along with the food, drug and dietary supplement labeling regulations on the Internet through links on FDA's web page www.fda.gov.

The following violations were noted:

The promotional brochure titled "*Calm Focus*" states, "...help children and adults with attention deficit hyperactivity disorder (ADHD)..." "Taking *Calm Focus* daily...is a great start in controlling ADD/ADHD." "Zinc - for blood sugar regulation, allergic reactions..." "Taurine...is used to treat ADHD." "Passion Flower...insomnia, and stress related disorders." "Rosemary-fights bacteria..." "Ginkgo Biloba...good for depression..." "Grape Seed...moderate allergic and inflammatory responses..." These statements cause your product to be a drug as defined in section 201(g)(1)(B) of the Act. Because we are unaware of any evidence that this product is generally recognized as safe and effective when used as labeled, it also is a new drug under section 201(p) of the Act.

Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application.

The product is further misbranded under Section 502(f)(1) of the Act, in that it fails to bear adequate directions for use, and under Section 502(a) of the Act, in that the labeling is false and misleading because it suggests that the product is safe and effective for its intended use. Neither safety nor effectiveness has been established.

Even if this product was not a drug and was to be deemed a dietary supplement, it would violate other provisions of the Act.

Specifically, the product label for *Better Way Kids Calm Focus* states, "A.D.H.D (ATTENTION DEFICIT HYPERACTIVITY DISORDER)," "*Calm Focus* is a natural approach to treating A.D.H.D." These claims are false and misleading in that they are not supported by sufficient scientific studies and therefore they cause your product to be misbranded under Section 403(a)(1) of the Act.


The immediate product label, as well as the labeling that accompanies the product, and the labeling that appears on your firm's Internet website (from which product can be purchased) cause your product to be misbranded.

This letter is not intended to be an all-inclusive list of the deficiencies in your product and its labeling. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. You should review the labeling for all of your products to assure that they are in compliance. We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

You should notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised labeling should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

You should direct your reply to Patricia Murphy, Compliance Officer at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any questions concerning this letter, please contact Ms. Murphy at 781-596-7758.

Sincerely,


Gail T. Costello
Director
New England District